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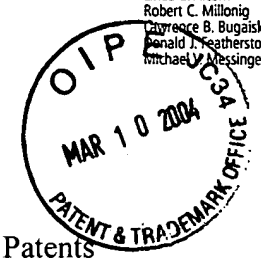
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*Admitted only in Maryland
· Admitted only in Virginia
•Practice Limited to Federal Agencies




March 10, 2004

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Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

***Art Unit 1651***

Re: U.S. Utility Patent Application
Appl. No. 10/694,189; Filed: October 28, 2003
For: **Defined Systems for Epithelial Cell Culture and Use Thereof**
Inventors: Judd *et al.*
Our Ref: 0942.4180003/RWE/FRC

Sir:

Transmitted herewith for appropriate action are the following documents:

1. Information Disclosure Statement;
2. Listing of the cited documents on Form PTO-1449 (10 sheets citing 58 documents);
3. A copy of document **AR10** cited on Form PTO-1449; and
4. One (1) return postcard.

It is respectfully requested that the attached postcard be stamped with the date of filing of these documents, and that it be returned to our courier. In the event that extensions of time are necessary to prevent abandonment of this patent application, then such extensions of time are hereby petitioned.

The U.S. Patent and Trademark Office is hereby authorized to charge any fee deficiency, or credit any overpayment, to our Deposit Account No. 19-0036.

Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.

Frank R. Cottingham
Attorney for Applicants
Registration No. 50,437

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Enclosures

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

| | |
|---|---|
| In re application of: | Confirmation No. 2747 |
| Judd *et al.* | Art Unit: 1651 |
| Appl. No. 10/694,189 | Examiner: *To be assigned* |
| Filed: October 28, 2003 | Atty. Docket: 0942.4180003/RWE/FRC |
| For: **Defined Systems for Epithelial Cell Culture and Use Thereof** | |




## Information Disclosure Statement

Commissioner for Patents
PO Box 1450
Alexandria, VA 22313-1450

Sir:

Listed on accompanying Form PTO-1449 are documents that may be considered material to the examination of this application, in compliance with the duty of disclosure requirements of 37 C.F.R. §§ 1.56, 1.97 and 1.98.

The Examiner's attention is directed to the following co-pending U.S. Patent Application, which is directed to related technical subject matter: U.S. Patent Application No. 09/028,514, Gorfien *et al.*, filed February 23, 1998 and submitted herewith as document **AR10**. A copy of this document is included.

The identification of this U.S. Patent Application is not to be construed as a waiver of secrecy as to this application now or upon issuance of the present application as a patent. The Examiner is respectfully requested to consider the cited application and the art cited therein during examination.

Copies of all other documents were previously cited by or submitted to the Office in an Information Disclosure Statement that complies with 37 C.F.R. § 1.98(a)-(c) in Application No. 09/695,926, Judd *et al.*, filed October 26, 2000, which is relied upon for

an earlier filing date under 35 U.S.C. § 120. Thus, copies of these documents are not attached. 37 C.F.R. § 1.98(d).

Where the publication date of a listed document does not provide a month of publication, the year of publication of the listed document is sufficiently earlier than the effective U.S. filing date and any foreign priority date so that the month of publication is not in issue. Applicants have listed publication dates on the attached PTO-1449 based on information presently available to the undersigned. However, the listed publication dates should not be construed as an admission that the information was actually published on the date indicated.

Applicants reserve the right to establish the patentability of the claimed invention over any of the information provided herewith, and/or to prove that this information may not be prior art, and/or to prove that this information may not be enabling for the teachings purportedly offered.

This statement should not be construed as a representation that a search has been made, or that information more material to the examination of the present patent application does not exist. The Examiner is specifically requested not to rely solely on the material submitted herewith.

This Information Disclosure Statement is being filed before the mailing date of a first Office Action on the merits. No statement or fee is required.

It is respectfully requested that the Examiner initial and return a copy of the enclosed PTO-1449, and indicate in the official file wrapper of this patent application that the documents have been considered.

The U.S. Patent and Trademark Office is hereby authorized to charge any fee deficiency, or credit any overpayment, to our Deposit Account No. 19-0036.

Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.

Frank R. Cottingham
Attorney for Applicants
Registration No. 50,437

Date: MAR. 10, 2004

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(202) 371-2600

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| FORM PTO-1449<br>INFORMATION DISCLOSURE STATEMENT | ATTY. DOCKET NO.<br>0942.1[illegible]/RWE/FRC | APPLICATION NO.<br>10/694,189 |
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| | APPLICANT<br>Judd *et al.* | |
| | FILING DATE<br>October 28, 2003 | GROUP<br>1651 |

**U.S. PATENT DOCUMENTS**

| EXAMINER INITIAL | | DOCUMENT NUMBER | DATE | NAME | CLASS | SUB-CLASS | FILING DATE |
|---|---|---|---|---|---|---|---|
| | AA1 | 4,533,637 | 08/06/1985 | Yamane *et al.* | 435 | 240 | 05/18/1982 |
| | AB1 | 4,673,649 | 06/16/1987 | Boyce *et al.* | 435 | 240 | 07/15/1983 |
| | AC1 | 4,743,679 | 05/10/1988 | Cohen *et al.* | 530 | 350 | 02/24/1986 |
| | AD1 | 4,767,704 | 08/30/1988 | Cleveland *et al.* | 435 | 68 | 10/07/1983 |
| | AE1 | 4,940,666 | 07/10/1990 | Boyce *et al.* | 435 | 240.2 | 12/09/1986 |
| | AF1 | 5,122,469 | 06/16/1992 | Mather *et al.* | 435 | 240.2 | 10/03/1990 |
| | AG1 | 5,189,148 | 02/23/1993 | Akiyama *et al.* | 530 | 399 | 07/03/1990 |
| | AH1 | 5,292,655 | 03/08/1994 | Wille, Jr. | 435 | 240.3 | 01/29/1990 |
| | AI1 | 5,316,938 | 05/31/1994 | Keen *et al.* | 435 | 240.31 | 12/18/1992 |
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|---|---|---|---|---|---|---|---|
| | AL1 | WO 90/08771 | 08/09/1990 | PCT | | | Yes No |
| | AM1 | EP 0 408 146 A2 | 01/16/1991 | Europe | | | Yes No |
| | AN1 | WO 92/05246 | 04/02/1992 | PCT | | | Yes No |
| | AO1 | EP 0 481 791 A2 | 04/22/1992 | Europe | | | Yes No |
| | AP1 | EP 0 531 733 A1 | 03/17/1993 | Europe | | | Yes No |

**OTHER (Including Author, Title, Date, Pertinent Pages, etc.)**

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| | AR | 1 | Boyce, S.T., and Ham, R.G., "Calcium-Regulated Differentiation of Normal Human Epidermal Keratinocytes in Chemically Defined Clonal Culture and Serum-Free Serial Culture," *J. Invest. Dermatol. 81*:33s-40s, The Williams and Wilkins Co. (1983) |
| | AS | 1 | Chaproniere-Rickenberg, D.M., and Webber, M.M., "Zinc Levels in Zinc-Stabilized Insulin are Inhibitory to the Growth of Cells In Vitro," *In Vitro 19(5)*:373-375, Tissue Culture Association (1983) |
| | AT | 1 | Daley, J.P., *et al.*, "Growth of Human Epidermal Keratinocytes in Keratinocyte Serum-Free Medium," *Focus 12(3)*:68-71, Life Technologies, Inc. (1990) |

| EXAMINER | DATE CONSIDERED |
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| | AB2 | 5,395,756 | 03/07/1995 | Igarashi | 435 | 69.4 | 04/04/1994 |
| | AC2 | 5,443,968 | 08/22/1995 | Takazawa *et al.* | 435 | 70.3 | 01/03/1994 |
| | AD2 | 5,461,030 | 10/24/1995 | Lindenbaum | 544 | 4 | 11/29/1993 |
| | AE2 | 5,474,931 | 12/12/1995 | DiSorbo *et al.* | 435 | 240.31 | 09/21/1993 |
| | AF2 | 5,573,957 | 11/12/1996 | Cardone *et al.* | 436 | 518 | 09/28/1994 |
| | AG2 | 5,576,194 | 11/19/1996 | Chan | 435 | 69.6 | 10/01/1993 |
| | AH2 | 5,631,159 | 05/20/1997 | Marshall *et al.* | 435 | 383 | 09/22/1993 |
| | AI2 | 5,633,162 | 05/27/1997 | Keen *et al.* | 435 | 384 | 03/04/1994 |
| | AJ2 | 5,641,647 | 06/24/1997 | Fischer *et al.* | 435 | 69.1 | 08/24/1993 |
| | AK2 | 6,103,529 | 08/15/2000 | Price *et al.* | 435 | 404 | 10/10/1997 |

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|---|---|---|---|---|---|---|---|
| | AL2 | WO 95/01434 | 01/12/1995 | PCT | | | Yes No |
| | AM2 | WO 97/34999 | 09/25/1997 | PCT | | | Yes No |
| | AN2 | WO 98/24883 | 06/11/1998 | PCT | | | Yes No |
| | AO | | | | | | Yes No |
| | AP | | | | | | Yes No |

**OTHER (Including Author, Title, Date, Pertinent Pages, etc.)**

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|---|---|---|---|
| | AR | 2 | Ethier, S.P., *et al.*, "Influence of Hormone and Growth Factor Interactions on the Proliferative Potential of Normal Rat Mammary Epithelial Cells In Vitro," *J. Cell. Physiol. 132*:161-167, Alan R. Liss, Inc. (1987) |
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| | AL | | | | | | Yes No |
| | AM | | | | | | Yes No |
| | AN | | | | | | Yes No |
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| | AS | 3 | Gospodarowicz, D., and Cheng, J., "Heparin Protects Basic and Acidic FGF From Inactivation," *J. Cell. Physiol. 128*:475-484, Alan R. Liss, Inc. (1986) |
| | AT | 3 | Green, W.N., *et al.*, "cAMP stimulation of acetylcholine receptor expression is mediated through posttranslational mechanisms," *Proc. Natl. Acad. Sci. USA 88*:854-858, National Academy of Sciences of the USA (1991) |

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| | AR | 4 | Hahm, H.A., and Ip, M.M., "Primary Culture of Normal Rat Mammary Epithelial Cells Within a Basement Membrane Matrix. I. Regulation of Proliferation by Hormones and Growth Factors," *In Vitro Cell. Dev. Biol. 26*:791-802, Tissue Culture Association (1990) |
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| | AT | 4 | Ham, R.G., "Formulation of Basal Nutrient Media," in *Methods for Preparation of Media, Supplements, and Substrata for Serum-Free Animal Cell Culture*, Barnes, D.W., *et al.*, eds., New York, Alan R. Liss, Inc., pp. 3-21 (1984) |

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| | AR | 5 | Imagawa, W., *et al.*, "Keratinocyte Growth Factor and Acidic Fibroblast Growth Factor Are Mitogens for Primary Cultures of Mammary Epithelium," *Biochem. Biophys. Res. Commun.* *204*:1165-1169, Academic Press, Inc. (1994) |
| | AS | 5 | Lambert, K.J., and Birch, J.R., "Cell Growth Media," in *Animal Cell Biotechnology*, Vol. 1, Spier, R.E., and Griffiths, J.B., eds., New York, Academic Press, Inc., pp. 85-122 (1985) |
| | AT | 5 | Marcelo, C.L., *et al.*, "Stratification, Specialization, and Prolferation of Primary Keratinocyte Cultures," *J. Cell. Biol.* *79*:356-370, The Rockefeller University Press (1978) |

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| | AL | | | | | | Yes No |
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**OTHER (Including Author, Title, Date, Pertinent Pages, etc.)**

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|---|---|---|---|
| | AR | 6 | Pirisi, L., *et al.*, "Transformation of Human Fibroblasts and Keratinocytes with Human Papillomavirus Type 16 DNA," *J. Virol.* *61*:1061-1066, American Society for Microbiology (1987) |
| | AS | 6 | Pittelkow, M.R., and Scott, R.E., "New Techniques for the In Vitro Culture of Human Skin Keratinocytes and Perspectives on Their Use for Grafting of Patients With Extensive Burns," *Mayo Clin. Proc.* *61*:771-777, Mayo Foundation for Medical Education and Research (1986) |
| | AT | 6 | Pittelkow, M.R., and Shipley, G.D., "Serum-Free Culture of Normal Human Melanocytes: Growth Kinetics and Growth Factor Requirements," *J. Cell. Physiol.* *140*:565-576, Alan R. Liss, Inc. (1989) |

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| | | | |
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| | AR | 7 | Price, F.M., *et al.*, "A New Culture Medium for Human Skin Epithelial Cells," *In Vitro 16*:147-158, Tissue Culture Association (1980) |
| | AS | 7 | Rheinwald, J.G., and Green, H., "Serial Cultivation of Strains of Human Epidermal Keratinocytes: the Formation of Keratinizing Colonies from Single Cells," *Cell 6*:331-344, MIT Press (1975) |
| | AT | 7 | Shipley, G.D., and Pittelkow, M.R., "Control of Growth and Differentiation In Vitro of Human Keratinocytes Cultured in Serum-free Medium," *Arch. Dermatol. 123*:1541a-1544a, American Medical Association (1987) |

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| | AK | | | | | | |

**FOREIGN PATENT DOCUMENTS**

| EXAMINER INITIAL | | DOCUMENT NUMBER | DATE | COUNTRY | CLASS | SUB-CLASS | TRANSLATION |
|---|---|---|---|---|---|---|---|
| | AL | | | | | | Yes No |
| | AM | | | | | | Yes No |
| | AN | | | | | | Yes No |
| | AO | | | | | | Yes No |
| | AP | | | | | | Yes No |

**OTHER (Including Author, Title, Date, Pertinent Pages, etc.)**

| | | | |
|---|---|---|---|
| | AR | 8 | Shipley, G.D., *et al.*, "Growth of Normal Keratinocytes and Fibroblasts in Serum-Free Medium Is Stimulated by Acidic and Basic Fibroblast Growth Factor," *J. Cell. Physiol. 138*:511-518, Alan R. Liss, Inc. (1989) |
| | AS | 8 | Turner, T., *et al.*, "Serum-Free Culture of Enriched Mouse Anterior and Ventral Prostatic Epithelial Cells in Collagen Gel," *In Vitro Cell. Dev. Biol. 26*:722-730, Tissue Culture Association (1990) |
| | AT | 8 | Watson, C.A., *et al.*, "Variability Among Human Umbilical Vein Endothelial Cultures," *Science 268*:447-448, American Association for the Advancement of Science (April 1995) |

| EXAMINER | DATE CONSIDERED |
|---|---|

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| FORM PTO-1449<br>INFORMATION DISCLOSURE STATEMENT | ATTY. DOCKET NO.<br>0942.4180003/RWE/FRC | APPLICATION NO.<br>10/694,189 |
|---|---|---|
| | APPLICANT<br>Judd *et al.* | |
| | FILING DATE<br>October 28, 2003 | GROUP<br>1651 |

**U.S. PATENT DOCUMENTS**

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|---|---|---|---|---|---|---|---|
| | AA | | | | | | |
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| | AP | | | | | | Yes No |

**OTHER (Including Author, Title, Date, Pertinent Pages, etc.)**

| | | | |
|---|---|---|---|
| | AR | 9 | Waymouth, C., "Preparation and Use of Serum-Free Culture Media," in *Methods for Preparation of Media, Supplements, and Substrata for Serum-Free Animal Cell Culture*, Barnes, D.W., *et al.*, eds., New York, Alan R. Liss, Inc., pp.23-68 (1984) |
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| | AT | 9 | Willey, J.C., *et al.*, "Relationship of Ornithine Decarboxylase Activity and cAMP Metabolism to Proliferation of Normal Human Bronchial Epithelial Cells," *J. Cell. Physiol.* *124*:207-212, Alan R. Liss, Inc. (1985) |

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**OTHER (Including Author, Title, Date, Pertinent Pages, etc.)**

| | | | |
|---|---|---|---|
| | AR | 10 | U.S. Patent Application No. 09/028,514, Gorfien *et al.*, filed February 23, 1998 (NOT PUBLISHED) |
| | AS | 10 | |
| | AT | 10 | |

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